SOLICITATION, OFFER AND AWARD

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) ▶	RATING	PAGE OF PAGES
		1 of 71

2. CONTRACT NUMBER	3. SOLICITATION NUMBER	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NUMBER
	223-00-MQSA	☐ SEALED BID (IFB) ☒ NEGOTIATED (RFP)	JAN. 28, 2000	

7. ISSUED BY CODE	8. ADDRESS OFFER TO *(If other than Item 7)*
DHHS/FDA/OFACS/DCPM/ORA Support & Assistance Management Bracnch, HFA-521 5600 Fishers Lane, Room 2129 Rockville, Maryland 20857	Type of Contract: Fixed Price Period of Performance:

NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder".

SOLICITATION

9. Sealed offers in original and 4 copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if handcarried, in the depository located in 5630 Fishers Lane, Rm 2129, Rockville, until 4:00P local time _____ *(Hour)* *(Date)*

CAUTION - LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in this solicitation.

10. FOR INFORMATION CALL: ▶	A. NAME	B. TELEPHONE *(NO COLLECT CALLS)* AREA CODE	NUMBER	EXT.	C. E-MAIL ADDRESS

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OFFER *(Must be fully completed by offeror)*

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within _____ calendar days *(60 calendar days unless a different period is inserted by the offeror)* from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT ▶ *(See Section I, Clause No. 52-232-8)*	10 CALENDAR DAYS (%)	20 CALENDAR DAYS (%)	30 CALENDAR DAYS (%)	CALENDAR DAYS (%)

14. ACKNOWLEDGMENT OF AMENDMENTS *(The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated):*	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR	CODE	FACILITY	16. NAME AND TITLE OF PERSON AUTHORIZED TO SIGN OFFER *(Type or print)*

15B. TELEPHONE NUMBER AREA CODE	NUMBER	EXT.	☐ 15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.	17. SIGNATURE	18. OFFER DATE

AWARD *(To be completed by Government)*

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION

22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: ☐ 10 U.S.C. 2304(c) ( ) ☒ 41 U.S.C. 253(c) (1)	23. SUBMIT INVOICES TO ADDRESS SHOWN IN *(4 copies unless otherwise specified)* ▶	ITEM G-3

24. ADMINISTERED BY *(If other than Item 7)* CODE	25. PAYMENT WILL BE MADE BY CODE

26. NAME OF CONTRACTING OFFICER *(Type or print)*	27. UNITED STATES OF AMERICA *(Signature of Contracting Officer)*	28. AWARD DATE

IMPORTANT - Award will be made on this Form, or on Standard Form 26, or by other authorized official written notice.

SECTION B - SUPPLIES OR SERVICES AND PRICE/COST

B-l - Background and Objectives

In performing the work as described in detail in Section C, C-l Scope of Work, the contractor shall review and consider the following:

A. Background Information

The Mammography Quality Standards Act of 1992 (MQSA) was signed into law on 27 October 1992. Interim regulations were published on 30 September 1994 and 03 April 1996. On 28 October 1997, the U.S. Food and Drug Administration (FDA) published final MQSA regulations in the Federal register. These regulations shall take effect on 28 April 1999. The intent of the Act is to ensure that women receive high quality mammography for early breast cancer detection by requiring the establishment of a federal certification and inspection program for mammography facilities. The Act authorizes FDA to obtain state and local assistance in enforcing the MQSA requirements including annual inspections of all certified mammography facilities.

B. Objective

This project is designed to obtain State and local support in the inspection of certified mammography facilities.

B-2 - Compensation

A. As consideration for full performance of the work stated in Part I, Section C - Scope of Work, the Government shall pay the contractor a total fixed price of $_____ for inspections, plus an estimated $_____ for cost reimbursement travel and labor for training, and/or $_____ for Continuing Education Units, for a total price of $_____.

B. Payment up to the full amount of this contract shall be contingent upon receipt and acceptance by the Government of inspection reports and proper invoices as required by Part I, Section F, F-1 - Reports/Deliverables and Section G, G-3 - Invoice Submission, and in accordance with the following schedule:

Section B (continued)

Schedule

Item	Unit Price	No. of Units	Total
Mammography Inspections	$_____	_____	$_____

C. Domestic Cost Reimbursement Travel Allowance (Incorporating Travel Policy)

The estimated cost for travel and training under this contract shall be subject to the provisions of FAR 52.232-20 “Limitation of Cost (APR 1984)” and FAR 52.216-7 “Allowable Cost and Payment (APR 1998)” in Part II, Section I.

Total expenditures for domestic travel (transportation, lodging, meals, and incidental expenses) not to exceed $_____ incurred for training in performance of this contract shall be allowed based on the Contractor’s travel policy.

D. Continuing Education for MQSA Inspectors

Total expenditures for each certified inspector to acquire 15 Mammography Continuing Education Units (MEUs) (registration and tuition fees, course materials, and if necessary, appropriate travel expenses) shall not exceed the appropriate allotment within the three year certification period. As a result of policy changes communicated in June 1998, the MEU allotment was changed as follows:

- Effective June 1998, newly trained inspectors and current inspectors entering their next three (3) year certification period shall be allotted $1,300.00
- Those remaining inspectors shall continue to utilize funds from their $1,800 allotment until their next re-certification period at which time the $1,300 allotment shall become effective.

Funds in the amount of $_____ for _____ inspectors are allotted for MEUs under this contract.

Section B (continued)

B-3 – Contract Schedule Modifications affected by Option Exercise

A. Upon execution of each option, an additional twelve (12) months will be added to the contract period of performance.

B. The following payment schedule(s) will be effective for the option year(s) of performance:

1. Option Year 1 (From _____ to _____)

a. By the addition of Option Year 1, the Government will pay to the Contractor the fixed price not to exceed $_____.

b. Payment Schedule

Item	Unit Price	No. of Units	Total
Mammography Inspections	$_____	_____	$_____

c. Continuing Education for MQSA Inspectors

Total expenditures for each certified inspector to acquire 15 Mammography Continuing Education Units (MEUs) (registration and tuition fees, course materials, and if necessary, appropriate travel expenses) shall not exceed the appropriate allotment within the three year certification period. As a result of policy changes communicated in June 1998, the MEU allotment was changed as follows:

- Effective June 1998, newly trained inspectors and current inspectors entering their next three (3) year certification period shall be allotted $1,300.00
- Those remaining inspectors shall continue to utilize funds from their $1,800 allotment until their next re-certification period at which time the $1,300 allotment shall become effective.

Funds in the amount of $_____ for _____ inspectors are allotted for MEUs under this contract.

Section B (continued)

2. Option Year 2 (From _____ to _____)

a. By the addition of Option Year 2, the Government will pay to the Contractor the fixed price not to exceed $_____.

b. Payment Schedule

Item	Unit Price	No. of Units	Total
Mammography Inspections	$_____	_____	$_____

c. Continuing Education for MQSA Inspectors

Total expenditures for each certified inspector to acquire 15 Mammography Continuing Education Units (MEUs) (registration and tuition fees, course materials, and if necessary, appropriate travel expenses) shall not exceed the appropriate allotment within the three year certification period. As a result of policy changes communicated in June 1998, the MEU allotment was changed as follows:

- Effective June 1998, newly trained inspectors and current inspectors entering their next three (3) year certification period shall be allotted $1,300.00
- Those remaining inspectors shall continue to utilize funds from their $1,800 allotment until their next re-certification period at which time the $1,300 allotment shall become effective.

Funds in the amount of $_____ for _____ inspectors are allotted for MEUs under this contract.

SECTION C - DESCRIPTION/SPECIFICATION/WORK STATEMENT

C-l - Scope of Work

Independently and not as an agent of the Government, the contractor shall furnish the necessary personnel, materials, services, facilities, and otherwise do all things necessary for or incident to the performance of the work as described below:

Description of Work to be Performed

I. Compliance Inspections of Certified Mammography Facilities

The contractor shall inspect mammography facilities that have been certified by the Food and Drug Administration (FDA) to perform mammography under the Mammography Quality Standards Act of 1992 (MQSA).

a. The following shall be accomplished:

Technical Considerations

The contractor shall be required to perform mammography facility inspections in conformance with the techniques, requirements and methodologies as detailed in the following and in subsequent revisions:

1. MQSA Inspection Procedures (Copies of the Facility Inspection Procedures and Compliance Program will be provided to the contractor via the inspector's laptop or via hardcopy. FDA will also provide training in the use of the procedures for all personnel performing MQSA inspections.

2. Inspection policies, Policy Guidance Help Guidance System and "All-Inspector" E-mails issued by DMQRP (accessible via the inspector's laptop).

Note: Information conveyed to the inspectors shall be accessed via the e-mail system accessible on the inspector's laptop. Those inspectors designated as "back-up" shall utilize a laptop from another inspector to obtain information.

Section C (cont)

3. Course I-IV Training Notebooks (provided to the inspectors at MQSA Inspector certification and Final Regulation training).

4. Good Guidance Policies (accessible via the website at http://www.fda.gov/cdrh/mammography and the inspector's laptop.)

5. Inspector support via the "inspector help desk" (for answers to specific inspector questions) at (301)827-1241 (emergency calls) or via email at helpdesk@cdrh.fda.gov.

6. FDA Compliance Program 7382.014, Mammography Facility Inspections.

Inspections

1. A total of ____ inspections shall be performed at certified facilities performing mammography. The FDA will perform __ non-federal facility inspections within the contractor's state/locality for the negotiated period of performance, unless otherwise noted. The FDA will provide the contractor with monthly lists of certified facilities in the state. Questions concerning the list should be directed to Mr. Malcolm Dennis, FDA/Division of Mammography Quality & Radiation Programs (DMQRP), at (301) 827-2961.

2. An inspection means the completion of the procedures in the documents entitled “Mammography Quality Standard Act (MQSA) - Facility Inspection Procedures” and “FDA Compliance Program 7382.014, Mammography Facility Inspections”, and any subsequent revisions.

The types of inspections that shall be conducted include the following:

• Annual Inspection - this is a mandated routine inspection conducted annually. The inspection shall be conducted no sooner than 10 months and no later than 14 months from the last routine annual inspection at a facility to assure compliance with MQSA. All new facilities shall be inspected within one year of being fully certified.

Section C (continued)

• Follow-up Reinspection - conducted to determine whether the facility has complied with the terms of their corrective action plan, based upon the deficiencies found during a previous inspection. These will only be conducted by FDA investigators who are certified MQSA inspectors, except in cases where no certified FDA inspector is available, the violations are substantial, and the re-inspection should not be delayed. Under these conditions, certified State MQSA inspectors may perform follow-up re-inspections only when requested and authorized by the FDA's Regional Radiological Health Representative (RRHR).

• Joint Audit Inspection - an inspection conducted by a certified inspector under the observation of an FDA auditor to assure that inspections are conducted properly. Audits will normally be conducted during an annual inspection and are required for each inspector during the course of the federal fiscal year (01 October through 30 September). Reference Section 2 - Requirements (Annual Audit) under "Maintenance of MQSA Inspector Certification" for additional audit requirements.

• Mentored Inspection - an annual inspection conducted by an inspector under the assistance of an MQSA certified inspector is termed a "mentored inspection". Mentored inspections are conducted as follows:

- To assist the inspector in need of performance improvements.
- To meet inspector certification requalification requirements.

The inspector is required to enter an "M" for mentored inspection, identify the mentoring inspector by ID # (number) and indicate the rationale for the mentored inspection in the internal remarks section of the inspection report.

3. All of the inspections conducted by the Contractor shall be of facilities that are certified by the FDA.

• Fully Certified Facilities

A fully certified facility has applied for and met accreditation standards under a six-month provisional

Section C (continued)

certification status from an FDA approved Accreditation Body or has completed the re-accreditation process. Issuance of the FDA three-year Mammography Facility Certificate means that the FDA:

- Acknowledges the facility's accreditation by an FDA-approved Accreditation Body.
- Certifies a facility as a mammography facility that can lawfully provide mammography services.
- Will make the facility name and address available to members of the public as a facility certified under MQSA.

NOTE: Fully certified facilities shall receive an annual MQSA inspection.

• Provisionally Certified Facilities

A provisionally certified facility has been issued a six-month provisional certificate because FDA received information from an FDA-approved accreditation body that the facility's application is sufficiently complete but still in progress. A provisional certificate allows a facility to legally perform mammography services for up to six months while completing the accreditation process. Once FDA is notified of the full accreditation of a facility, FDA issues a certificate fully certifying the facility.

- Inspection of new provisionally certified facilities should be avoided unless there is a compelling reason not to do so (e.g., questions concerning clinical image quality). In these cases, the contractor shall consult with and obtain the concurrence of the cognizant Regional Radiological Health Representative (RRHR) before scheduling an inspection.

• Provisionally Reinstated Facilities

A provisionally reinstated facility refers to a facility previously certified and currently undergoing accreditation body review. This means that the FDA acknowledges that the facility is certified by the FDA to lawfully provide mammography services for up to six months while completing the re-accreditation process.

Section C (continued)

Once the FDA is notified of the full reinstatement of the facility, FDA issues a certificate fully certifying the facility.

- Provisionally reinstated facilities are subject to inspection and may, in certain cases, be considered higher priority than fully certified facilities due to a history of problems preventing accreditation. In these cases, the contractor shall consult with and obtain the concurrence of the cognizant Regional Radiological Health Representative (RRHR) before scheduling an inspection.

4. Facility Notification - The Contractor shall provide the facility sufficient time to prepare for the FDA Standard MQSA inspection. Two to three business weeks is recommended. However, no less than five (5) working days notification is required before the beginning of the inspection, unless authorized by the RRHR to inspect the facility without prior notice. Notification will be provided to the facility in writing(preferably by facsimile) using the FDA standard notification, unless the facility waives the need for written notice. A State notification format may be used if it has been approved by the Contract Project or Co-Project Officer.

5. Facility Status Changes - The Contractor shall immediately advise the cognizant FDA Regional Radiological Health Representative (RRHR) of changes in facility status (e.g., closure, change in name or address, facility is performing mammography without a certificate provided by FDA). These changes shall also be reflected in the monthly reports. Upon notification of the change in facility status, the contractor shall direct the facility to their respective Accrediting Body to effect the official change. NOTE: The FDA cannot recognize the facility modification without official notice via the cognizant Accrediting Body and in the case of a closed facility without the return of the FDA certificate.

6. Patient Data - No patient name, address, or any other information that can be used to identify an individual, shall be collected from facilities under this contract.

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7. Inspection Record/Reports - A computer generated inspection record shall be used for each inspection. The specific inspection data for each inspection shall be recorded on the portable computer system supplied by the FDA (or a FDA approved contractor owned system - reference *Attachment 1*, entitled “Minimum Specifications for Laptops used for MQSA Inspections”) and uploaded into FDA's Mammography Program Reporting and Information System (MPRIS) via telecommunication.

Note (1): The contractor shall obtain approval from DMQRP prior to loading any non-FDA provided software on the computer.
Note (2): The State is responsible for the upkeep and repairs of state-owned computers and associated equipment. Additionally the state is responsible for any lost, damaged, or misuse to FDA equipment, beyond normal wear and tear.

Reports shall be furnished in the computerized format developed by FDA. Instructions for completing the computer generated inspection record are contained in the MQSA Facility Inspection Procedures.

b. Inspection Findings

1. Level 1 Findings - The Contractor shall notify the FDA regional and district office when the inspection results indicate a level 1 finding. A facsimile copy of the inspection findings report shall be sent to the designated FDA contact as soon as possible. If it is not possible to send a facsimile within five (5) days, the Contractor shall notify the FDA RRHR field office contact by telephone. When serious findings are detected during an inspection, FDA will draft a warning letter to the facility. The FDA may request the contractor review the letter to ensure that the letter accurately represents the actual inspection findings.

2. Level 2 Findings and Repeat Level 3 Findings - Level 2 findings and Repeat level 3 findings found during an inspection will warrant a written response from the facility to FDA with a copy to the Contractor. Upon receipt of the facility response letter, the FDA will evaluate and respond to the facility. The FDA will evaluate and respond to the facility.

Section C (continued)

The FDA will contact the State if FDA requires any state input or comments on the response. A copy of the FDA response will be provided to the State. For certain types of findings and unsuccessful corrective action by facilities, a limited number of re-inspections may be required. FDA will notify the Contractor when re-inspections are required and if they are to be performed by the Contractor or FDA.

c. Compliance Actions

Compliance Actions are not provided for under this contract. However, the Contractor may wish to pursue any necessary compliance follow-up to findings subject to the state's jurisdiction. If the contractor pursues compliance follow-up under their state's jurisdiction, the following procedures apply:

1. Adverse Action Taken Against a Facility Under State Authority

The Contractor shall report to the RRHR or other designated contact, any adverse action taken against a facility under state authority within ten (10) working days of the event in instances where a significant finding has occurred that would result in FDA taking action under MQSA. An adverse action could include the following:

- facility license suspension (temporary or permanent),
- facility license revocation, restrictions or similar sanctions, fines and penalties (civil or administrative),
- patient/physician notification
- remedial or corrective action plans required by state authorities,
- prosecution and convictions under state laws relating to fraud and abuse, false billings or kickbacks, and
- other state action (identify and provide description).

2. Providing Adverse Action Information

The FDA is required, pursuant to MQSA, to compile certain information about mammography facilities, and make it available to physicians and the general public (42 U.S.C. 263b(1)), who should find this information useful in evaluating the performance of mammography facilities.

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The report, submitted to Congress annually, will include explanatory information necessary to help in the interpretation of the information compiled.

One required category of information to be compiled is a list of mammography facilities against which states have taken adverse actions. In addition, we are also seeking information about which states have instituted a patient notification rule applicable to mammography.

Contractors shall complete and submit the attached form (Attachment 2, entitled "Adverse Actions Report Form") or report the information directly in the body of the monthly report to detail both adverse actions and patient notification information (see Part II and appropriate blocks under Part I) in the monthly progress report. A separate form is required for each facility against which an adverse action was taken. Report only those State cases that are comparable to those that could be the subject of adverse actions under MQSA. For the purpose of this report, adverse events include:

1. Facility license suspension(temporary or permanent).
2. Facility license revocation.
3. Restrictions or similar sanctions.
4. Patient/Physician notification
5. Fines/Penalties (civil or administrative).
6. Remedial or corrective action plans required by State authorities (report only those State cases that are comparable to those that could be the subject of adverse actions under MQSA).
7. Prosecution and conviction under State laws relating fraud and abuse, false billings or kickbacks.
8. Other State action-identify and provide description. (Report only those State cases that are comparable to those that could be the subject of adverse actions under MQSA).

The information for each cited mammography facility should include the following items:

1. Name of facility and address of the mammography facility;
2. MQSA facility identification number if known;
3. Current status of the facility;

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4. Date of action (month/day/year);
5. Reason for action (reference Attachment 2 for codes);
6. Description of corrective action;
7. Date of corrective action/reinstatement (month/day/year);
8. Was patient notification conducted? (if yes, go to #9);
9. Was patient notification conducted voluntarily by the facility or under State law?

Note: If there were no adverse Actions taken, include one copy of the form with "No Adverse Actions" or "N/A" written clearly on the form or state this information on the monthly report. If your State currently does not have authority to impose adverse actions, please indicate so on the form or in the monthly report.

d. Inspectors

1. Inspector Certification Training - All inspections under this contract shall be conducted by personnel who have successfully completed the required training and mentoring, and are fully certified by the FDA to perform inspections under MQSA. The training for inspector certification will consist of courses taught under the auspices of the FDA and shall require the inspector to pass specific examinations. All new inspectors shall meet the Educational Requirements for New MQSA Inspectors policy requirements (Attachment 3, entitled "Educational Requirements for New MQSA Inspectors") before taking the MQSA training courses.

In determining a State's need for a trained inspector, FDA shall reference Attachment 5, entitled, "State Contract Policy: Training MQSA Inspectors and Assignment of Inspection Equipment."

2. Maintenance of MQSA Inspector Certification - MQSA certification is assessed annually - each federal fiscal year from 01 October through 30 September - by the FDA MQSA Auditor to determine conformance with requirements as described below:

- Continuing Education Requirements:

- Inspectors shall participate in continuing education activities. The current requirement is for each certified inspector to teach or earn a minimum of fifteen (15) mammography

Section C (continued)

education units (MEUs) during a 36-month period in accordance with the "Mammography Continuing Education (MEU) Policy for MQSA Certified Inspector" as set forth in Attachment 4. The funding of MEU training and the appropriateness of proposed costs shall be approved - in advance - by the Conference of Radiation Control and Program Directors.

- As per the Continuing Education Policy, inspectors shall provide documentation (i.e., certificates) of their attendance at, and completion of, the courses to the FDA MQSA Auditor to validate MEUs earned. Additionally, documentation of final funds expended shall be provided to CRCPD.

Continuing Experience:

- Inspectors shall maintain "active" certification status in accordance with the "MQSA Certified Inspector Continuing Experience Policy" by performing a minimum number of 24 (twenty-four) inspections during a 24 month period as specified in the policy (Attachment 6). FDA MQSA Auditors shall verify conformance with the requirement at the annual federal fiscal year (01 October - 30 September) audit. Inspectors should be prepared to provide documentation of their conformance with the policy.

- Annual Audit:

MQSA Inspectors shall receive a satisfactory Audit from a certified MQSA auditor during each federal fiscal year (01 October - 30 September) or satisfactorily complete re-mediation requirements if audit results warrant. The audit shall consist of observation of the physical measurements completed on the mammography systems; film processor and darkroom; physical examination of the QA, personnel and medical records, medical physicist report and medical audit system and entering the inspection data in the Mammography Program and reporting Information System (MPRIS) and conformance with inspector continuing education and experience requirements. Of equal importance will be the auditor observing the inspector's personal interaction with facility personnel and the inspector's ability of presenting significant findings during the exit interview with facility management. Significant findings are those that would impact upon the ability to accurately diagnosis breast cancer. Additional audits may be performed if serious deficiencies are observed in personnel interactions, physical

Section C (continued)

measurements, records examination or conducting the exit interview.

- Review of MQSA Inspection Records:

The auditor shall review a sample of the MQSA Inspection Records submitted by each certified inspector. Ten percent of the inspection records submitted by each inspector will be reviewed for indication of performance problems. If a review of these records indicate performance problems, additional joint audits of the inspections or remedial training may be scheduled to correct the observed deficiencies.

- Review Requirements:

All MQSA Inspectors shall keep up to date on MQSA policy changes and other important issues related to MQSA inspection procedures by logging on to the MPRIS system on a regular basis, but not less than once a month, to download and review Inspector Newsletters, review all inspector e-mail, software upgrades, and other pertinent documents.

NOTE (1) : Training on the use of the computers, software, and programs will be provided by FDA to inspectors, through training courses, teleconferences, workshops, the RRHR, DMQRP staff and the FDA MQSA auditor.

NOTE(2) : The contractor shall notify the cognizant FDA Regional Radiological Health Representative (RRHR) in writing as inspectors leave the MQSA Inspection program or change their inspector status (e.g., backup inspector modification) to coordinate the return of FDA issued equipment, FDA issued "laptop" computers, and FDA issued inspector credentials.

- Inspection Questions/Problems:

Any questions or problems resulting from the use of these inspection procedures or testing equipment furnished by FDA shall be reported to the cognizant FDA RRHR and DMQRP. DMQRP may be reached via telephone and/or laptop via the following:

- DMQRP Help Desk phone line (08:30am - 5:00pm EDT): (301) 827-1241 (Emergency Calls)
- DMQRP Help Desk e-mail: mailto:helpdesk@cdrh.fda.gov (for non emergency inquiries)

Section C (continued)

- Questions from facilities: Any questions raised by facilities specific to the application of the MQSA regulations (e.g. policy questions) shall be directed to the FDA/MQSA facility hotline at 1-800-838-7715 or the MQSA website at www.fda.gov/cdrh/mammography. Questions concerning inspection findings shall be forwarded to the appropriate RRHR and FDA District Office. Questions regarding the "day-to-day" operations from the facility should be handled by the facility via the appropriate facility personnel. Questions concerning accreditation shall be referred back to the facility who should contact their respective accreditation body.

- Instrumentation/Calibration:

The radiation measuring instruments and applicable testing equipment, including the portable computer system, will be furnished by FDA for use in this contract, unless comparable equipment is provided by the Contractor.

1. With the approval of the Division of Mammography Quality and Radiation Programs, the Contractor may use their own radiation measuring instruments and applicable testing equipment, provided this equipment is calibrated by FDA and will produce the same test results as that produced by FDA supplied equipment.

2. FDA provides annual calibration of FDA provided sensitometers and densitometers used in support of MQSA inspections. (See Attachment 7, entitled “Monthly Calibration 2000”). Upon the return of calibrated equipment, new control film shall be supplied to each inspector.

II. Dissemination of Information

a. Information generated by the Contractor (Inspection Reports) in the performance of this contract may be released to the public in accordance with applicable State laws. The Contractor shall provide the Contracting Officer one copy of the information/material released, along with the name and address of the requester, within thirty calendar days after receipt of the request, via the monthly report.

b. The state inspector shall notify the facility of the preliminary inspection results during the exit interview in

Section C (continued)

accordance with FDA Compliance Program 7382.014. A copy of the inspection findings shall be:

• left at the facility at the completion of the inspection, or
• sent to the facility no later than five (5) working days from the date of the inspection.

NOTE: If Level 1 or Level 2 findings are involved, the shall leave a copy of the inspection report with the facility at the conclusion of the onsite inspection.

c. Patient Data – No patient name, address or any other information that can be used to identify an individual, shall be collected from facilities inspected under this contract.

d. The Contractor, as part of its quality control methods, shall be responsible for investigating, resolving and responding in writing to facilities who raise inspector issues (complaints and compliments), estimated at approximately 1 issue per contract period of performance. FDA shall provide samples of response letters. The FDA point of contact for samples is Ms. Joanne Choy, FDA/DMQRP at (301) 827-2963. Copies of all communications shall be provided to FDA via the monthly report.

III. Quality Assurance Provisions

A. Contractor performance will be evaluated by FDA throughout the duration of the contract. This will be accomplished by various methods including review of inspection records and joint State-federal inspections (audit inspections). The FDA may also conduct audit inspections independently of State inspections, at a date after the State inspection, to evaluate the adequacy of State inspections.

Results of all FDA quality assurance reviews that pertain to the Contractor will be furnished to the Contractor.

B. The FDA will also monitor inspector performance. The FDA will provide to the Contractor relevant information on the monitoring of inspector performance for the purpose of identification of any area where improvement of inspector performance is required.

Section C (continued)

C. A sample of inspection records will be reviewed by FDA to verify that required data and information is complete and accurate. During a twelve (12) month period, the FDA regional or district office will request the Contractor to send a minimum of two inspection reports with the phantom image films and compression alignment films for each certified inspector. The reports will be selected at random by FDA and all records and films will be returned to the Contractor at the completion of the audit.

If an inspection record is found to be unacceptable to FDA, the Contractor will be advised and given an opportunity to correct the report or submit a new inspection record.

D. The contractor, as part of its quality control methods, shall be responsible for investigating, resolving, and responding in writing to facilities who raise inspector issues (complaints and compliments), estimated at approximately one (1) issue per contract period of performance. FDA shall provide samples of response letters. The FDA point of contact for samples is Ms. Joanne Choy, FDA/DMQRP at (301) 827-2963. Copies of all communications shall be provided to FDA via the monthly report.

- Minimum Inspection Requirements:

Inspectors shall maintain "active" certification status in accordance with the "MQSA Certified Inspector Continuing Experience Policy" by performing a minimum number of 24 (twenty-four) inspections during a 24 month period as specified in the policy (Attachment 6). FDA MQSA Auditors shall verify conformance with the requirement at the annual federal fiscal year (01 October - 30 September) audit. Inspectors should be prepared to provide documentation of their conformance with the policy.

SECTION D - PACKAGING AND MARKING

D-1 - Marking Instructions for Reports

This section is not applicable to this solicitation/contract.

SECTION E - INSPECTION AND ACCEPTANCE

E-1 - Inspection and Acceptance

Pursuant to the appropriate inspection clause as provided below, final inspection and acceptance of all items called for by this contract shall be made by the FDA Contracting Officer at the Food and Drug Administration, ORA Support and Assistance Management Branch, HFA-521, 5600 Fishers Lane, Room 2129, Rockville, Maryland 20857.

E-2 - FAR 52.252-2, Clauses Incorporated by Reference. (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

http://www.arnet.gov.far

I. FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSES

FAR 52.246-4, Inspection of Services - Fixed Price. (AUG 1996)

SECTION F - DELIVERIES OR PERFORMANCE

F-l - Reports/Deliverables

The contractor shall submit the following reports:

A. Inspection Reports

The Contractor shall complete the computer generated inspection record. Inspection records shall be submitted to the FDA's central computer system via telecommunication means using the FDA supplied portable computer (or Contractor supplied computer equipment, with approval by FDA). Inspection reports and supporting documentation must be submitted no later than five (5) working days after completion of an inspection.

B. Monthly Progress Reports

The Contractor shall submit to the Government monthly technical reports describing progress of the program. These reports shall include the following information:

1. Facility Inspected - A list of the facilities inspected during the reporting period including:

- facility name
- address
- identification number
- date of inspection
- inspector name
- level of finding(s) detected

2. Cumulative Inspections Performed - A cumulative total of the number of inspections performed since the beginning of the contract period of performance.

3. Current Problems - An indication of any current problems which may impede progress and proposed corrective action.

4. Mammography Education Unit (MEU) Activity - A description of any continuing education activities conducted during the reporting period with the following:

- name of participant
- date and type of training attended

Section F (continued)

- MEUs earned
- cost to be invoiced under the contract

5. Work to be Performed - A brief discussion of work to be performed during the next reporting period.

6. State Adverse Actions - The FDA is required, pursuant to MQSA law, to compile certain information about mammography facilities, and make it available to physicians and the general public in accordance with 42U.S.C. 263b(1), who should find this information useful in evaluating the performance of mammography facilities. The report, submitted by FDA to Congress annually, includes explanatory information necessary to help in the interpretation necessary to help in the interpretation of the information compiled.

   One required category of information to be compiled is a list of mammography facilities against which states have taken adverse actions. In addition, we are also seeking information about which states have instituted a patient notification rule applicable to mammography.

   Contractors shall complete and submit the attached form (Attachment 2), entitled “Adverse Actions Report Form” or report the information in the monthly report to detail both adverse actions and patient notification information (see Part II and appropriate blocks under Part I) in the monthly report. A separate form is required for each facility against which an adverse action was taken. Report only those State cases that are comparable to those that could be the subject of adverse actions under MQSA. For the purposes of this report, adverse events include:

- facility license suspension (temporary or permanent),
- facility license revocation, restrictions or similar sanctions, fines and penalties (civil or administrative),
- patient/physician notification
- remedial or corrective action plans required by state authorities,
- prosecution and convictions under state laws relating to fraud and abuse, false billings or kickbacks, and
- other state action (identify and provide description).

Section F (continued)

The information for each cited mammography facility in the monthly report under State Adverse Actions shall include the following items:

1. The name of the facility and address of the mammography facility,
2. MQSA facility identification number, if known,
3. Current status of the facility,
4. Date of action (month/day/year)
5. Reason for action (reference Attachment 1 for codes)
6. Description of corrective action,
7. Date of corrective action/reinstatement (month/day/yr)
8. Was patient notification conducted? (if yes, go to #9)
9. Was patient notification conducted voluntarily by the facility or under State law?

NOTE: If there was no Adverse Action taken, include one copy of the form with "No Adverse Action" or "NA" written clearly on the form or state this information on the monthly report.

7. Changes to Inspector Information - Changes in Inspector status, phone numbers, mail addresses, and/or names shall be included in the monthly report.

8. Facility Status Changes - The contractor shall immediately advise the FDA/RRHR of any changes in facility status (closure, address change, name change, operating status, operating without a permit, etc.).

9. Inspector Quality Assurance Issues - Copies of Communications concerning Inspector Quality Assurance Issues investigated and responded to by the contractor.

10. Copies of information/material released to the public in accordance with applicable State laws, along with the name and address of the requester, within thirty calendar days after receipt of the request, via the monthly report.

A Recommended format for monthly progress report is provided as Attachment 8.

- Monthly progress reports will be prepared and submitted via mail, facsimile or e-mail no later than the last day of the

Section F (continued)

subsequent month (i.e., October's Monthly report is due no later than 30 November).

Four (4) copies of the Monthly Report shall be distributed to the following:

- **(1)** The cognizant Regional Radiological Health Representative (RRHR).

- **(2)**Food and Drug Administration
  Division of Federal-State Relations, HFC-150
  Attn.: MQSA Project Officer
  5600 Fishers Lane, Room 12-07
  Rockville, Maryland 20857

  Fax: (301)443-2143
  e-mail: stoigo@ora.fda.gov
  POC: Steve Toigo, (301)827-2906

- **(3)**Food and Drug Administration
  ORA Support and Assistance Management
  Branch, HFA-521
  Attn.: Contract Specialist
  5600 Fishers Lane, Room 2129
  Rockville, Maryland 20857

  Fax: (301)827-7103
  e-mail: @oc.fda.gov
  POC: (301)827-

- **(4)**Food and Drug Administration
  Div. of Mammography Quality & Radiation
  Programs, HFZ-240
  Attn.: Inspection Support Branch
  1350 Piccard Dr., Room 220D
  Rockville, Maryland 20850

  Fax: (301)594-3306
  e-mail: jkc@cdrh.fda.gov
  POC: Joanne Choy, (301)827-2963

***IMPORTANT NOTE: Vouchers/Invoices cannot be approved without Monthly Reports. Therefore, timely submission is critical to expedite voucher/invoice processing**.

Section F (continued)

F-2 – Period of Performance

Performance of this contract shall begin on _____ and Shall not extend beyond _____.

SECTION G - CONTRACT ADMINISTRATION DATA

G-1 - Project Officer

The Project Officer responsible for the acceptance of work provided hereunder will be designated by separate correspondence.

G-2 - Project Director

The performance of the work required by this contract will be conducted for the State under the direction of _____.

G-3 - INVOICE SUBMISSION

1. Fixed Price - Quarterly (Letter of Credit)

____ Letter of Credit No:_____

OR

2. Fixed Price - Quarterly

The Contractor shall submit vouchers or invoices in accordance with the FAR 52.232-25 "Prompt Payment (JUN 1997)," and FAR 52.232-33 “Mandatory Information for Electronic Funds Transfer Payment (May 1999), in Part II, Section I:

A. In accordance with clause 52.232-33, **all** payments made under this contract shall be made using electronic funds transfer through the Automated Clearing House (ACH). The Contractor shall provide the following information to the Food and Drug Administration, Office of Financial Management, Systems Accounting Branch, HFA-120, 5600 Fishers Lane, Rockville, MD 20857 no later than 14 days prior to submission of the first invoice:

Section G (continued)

1. Routing transit number of the financial institution receiving payment.

2. Number of account to which funds are to be deposited.

3. Type of depositor account ("C" for checking, "S" for savings).

B. An original and five (5) copies shall be submitted to the attention of the designated Contract Specialist at the following address:

DHHS/FDA/ORA Support and Assistance Management
Branch, HFA-521
5600 Fishers Lane, Room 2129
Rockville, Maryland 20857

C. In addition, one informational copy of all vouchers shall be submitted to the Co-Project Officer in the Regional/District Office designated by separate correspondence.

G-4 - Government Property - Authorization - Transfer

A. The Contractor is authorized the retention and use of the equipment listed below. The accountability of this equipment is hereby transferred to this contract from Contract No. 223-9 .

Item	Quantity	Estimated Value
Field Inspection Test Kit(s)		$16,000.00 each

B. This kit includes the following items:

1. Aluminum Filter (0.1 mm thick, 5 pieces)
2. Carrying Case (with insert)
3. Chamber Test Support (including tripod)
4. Densitometer
5. Sensitometer
6. Fog Folder
7. Inspection Light
8. Magnifying Glass

Section G (continued)

9. MDH 1015 Monitor
10. Control Film (1 box provided at annual calibration)
11. Mammography Probe (10X-6M)
12. CDRH Breast Phantom
13. Ruler
14. Stop Watch
15. Tape Measure
16. Intel Pentium Portable PC with modem, mouse, and associated cables (est. value @ $3,100.00) (Reference Attachment 1)
17. Canon BJ-30 Bubblejet printer and associated cables (est. value @ $351.00)
18. Printer and Laptop Carrying Case (est. value @ $85.00)
19. MQSA Inspector ID Badge

C. The inspection record format will be furnished to the Contractor with the portable computer system. With the approval of the Division of Mammography Quality and Radiation Programs (DMQRP), the Contractor may use their own computers and software for the recording of inspection data, provided that the inspection data is the same as that produced by FDA supplied equipment and software. The Contractor shall obtain approval from DMQRP before loading any state owned software on the FDA computer.

D. Equipment return - Upon the departure or reassignment of an inspector, **ALL** equipment shall be returned to DMQRP as soon as practicable, unless stated otherwise by DMQRP to the following address:

Attention: Stephanie Belella
Tech Center, room 253
16071 Industrial Drive
Gaithersburg, MD 20877

E. Additional Equipment - Unless stated otherwise, no other equipment or supplies are provided under this contract.

F. In addition to the applicable Government Property Clause in Part II, Section I, the contractor shall comply with the provisions of DHHS publication, Contractor's Guide for Control of Government Property, 1990, which is incorporated by reference. This Handbook is available upon request.

Section G (continued)

G-5 - Government Furnished Property

A. Pursuant to the applicable "Government Property" clause in Part II, Section I, the items listed below will be delivered to the Contractor upon completion of the required FDA training.

Item	Quantity	Estimated Value
Field Inspection Test Kit(s)	___	$16,000.00 each

B. This kit includes the following items:

1. Aluminum Filter (0.1 mm thick, 5 pieces)
2. Carrying Case (with insert)
3. Chamber Test Support (including tripod)
4. Densitometer
5. Sensitometer
6. Fog Folder
7. Inspection Light
8. Magnifying Glass
9. MDH 1015 Monitor
10. Control Film (1 box provided at annual calibration)
11. Mammography Probe (10X-6M)
12. CDRH Breast Phantom
13. Ruler
14. Stop Watch
15. Tape Measure
16. Intel Pentium Portable PC with modem, mouse, and associated cables (est. value @ $3,100.00) (Reference Attachment 1)
17. Canon BJ-30 Bubblejet printer and associated cables (est. value @ $351.00)
18. Printer and Laptop Carrying Case (est. value @$85)
19. MQSA Inspector ID Badge

C. The inspection record format will be furnished to the Contractor with the portable computer system. With the approval of the Division of Mammography Quality and Radiation Programs (DMQRP), the Contractor may use their own computers and software for the recording of inspection data, provided that the inspection data is the same as that produced by FDA supplied equipment and software. The Contractor shall obtain

Section G (continued)

approval from DMQRP before loading any state owned software on the FDA computer.

D. Equipment return - Upon the departure or reassignment of an inspector, **ALL** equipment shall be returned to DMQRP as soon as practicable, unless stated otherwise by DMQRP to the following address:

Attention: Stephanie Belella
Tech Center, room 253
16071 Industrial Drive
Gaithersburg, MD 20877

E. Additional Equipment - Unless stated otherwise, no other equipment or supplies are provided under this contract.

F. In addition to the applicable Government Property Clause in Part II, Section I, the contractor shall comply with the provisions of DHHS publication, Contractor's Guide for Control of Government Property, 1990, which is incorporated by reference. This Handbook is available upon request.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

H-1 - Release of Information

A. Information generated by the contractor (Inspection Reports) in the performance of this contract may be released to the public in accordance with applicable state laws. The contractor shall provide to the Contracting Officer one copy of the information/material released, along with the name and address of the requester, within thirty calendar days after receipt of the request.

B. Guidance for providing information to mammography facilities inspected under this contract is included in FDA Compliance Program 7382.014, Mammography Facility Inspections and similar information is provided in the MQSA Inspection Procedures. The specific procedures to be used for notifying facilities of preliminary inspectional findings is covered in the FDA training courses that all contract personnel attend.

SECTION I - CONTRACT CLAUSES

I-1 - 52.252-2 Clauses Incorporated by Reference.(FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

http://www.arnet.gov.far

A. Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clauses

FAR Clause No.	Title & Date
52.203-3	Gratuities (APR 1984)
52.203-5	Covenant Against Contingent Fees (APR 1984) Government. (JUL 1995)
52.203-7	Anti-Kickback Procedures (JUL 1995)
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (JAN 1997)
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity (JAN 1997)
52.203-12	Limitations on Payments to Influence Certain Federal Transactions (JUN 1997)
52.204-4	Printing/Copying Double-Sided on Recycled Paper (JUN 1996)
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (JUL 1995)
52.215-2	Audit and Records - Negotiation (JUN 1999)
52.215-8	Order of Precedence-Uniform Contract Format (OCT 1997)
52.215-10	Price Reduction for Defective Cost or Pricing Data (OCT 1997)
52.216-5	Price Redetermination – Prospective (OCT 1997)
52.216-7	Allowable Cost and Payment (APR 1998)
52.217-6	Option for Increased Quantity (MAR 1989)
52.217-9	Option to Extend the Term of the Contract (NOV 1999)
52.219-8	Utilization of Small Business Concerns (OCT 1999)
52.222-3	Convict Labor (AUG 1996)
52.222-21	Prohibition of Segregated Facilities (FEB 1999)

Section I (continued)

52.222-26	Equal Opportunity (FEB 1999)
52.222-35	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era (APR 1998)
52.222-36	Affirmative Action For Workers with Disabilities (JUN 1998)
52-222-37	Employment Reports On Disabled Veterans and Veterans of the Vietnam Era (JAN 1999)
52.223-2	Clean Air and Water (APR 1984)
52.223-6	Drug-Free Workplace (JAN 1997)
52.227-1	Authorization and Consent (JUL 1995)
52.229-4	Federal, State, and Local Taxes (Noncompetitive Contract) (JAN 1991)
52.232-9	Limitation on Withholding of Payments (APR
52.232-17	Interest (JUN 1996)
52.232-20	Limitation of Cost (APR 1984)
52.232-23	Assignment of Claims (JAN 1986)
52.232-25	Prompt Payment (JUN 1997)
52.232-33	Mandatory Information for Electronic Funds Transfer Payment (MAY 1999)
52.233-1	Disputes (DEC 1998)
52.233-3	Protest After Award (AUG 1996)
52.242-1	Notice of Intent to Disallow Costs (APR 1984)
52.243-1	Changes - Fixed Price (AUG 1987) – Alternate V (APR 1984)
52.245-2	Government Property (Fixed-Price Contracts) (DEC 1989) - Alternate I (APR 1984)
52.246-23	Limitation of Liability (FEB 1997)
52.249-5	Termination for Convenience of the Government (Educational and Other Nonprofit Institutions) (SEPT 1996)

B. Department of Health and Human Services Acquisition Regulation (HHSAR) (48 CFR Chapter 3) Clauses

352.202-1	Definitions (JAN 1997)--Alternate
352.249-14	Excusable Delays (APR 1984)
352.270-4	Pricing of Adjustments (APR 1984)
352.270-6	Publication and Publicity (JUL 1991)
352.270-7	Paperwork Reduction Act (APR 1984)

SECTION J - LIST OF ATTACHMENTS

The following attachments are incorporated into this solicitation/contract.

Attachment	1 -	Minimum specifications for laptops used for MQSA inspections
Attachment	2 -	Adverse Actions Report Form
Attachment	3 -	Educational Requirements for New MQSA Inspectors
Attachment	4 -	Mammography Continuing Education Unit (MEU) Policy
Attachment	5 -	State Contract Policy
Attachment	6 -	MQSA Certified Inspector Continuing Experience Policy
Attachment	7 -	Monthly Calibration 2000
Attachment	8 -	Recommended Monthly Report Format
Attachment	9 -	Disclosure of Lobbying Activities

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations and Certifications

To Be Completed by the Offeror/Bidder: (The Representations and Certifications must be executed by an individual authorized to bind the offeror/bidder.)

The offeror/bidder makes the following Representations and Certifications as part of its proposal (check or complete all appropriate boxes or blanks on the following pages).

_____
Solicitation No.

_____
Name of Offeror/Bidder

_____
Signature of Authorized Individual

_____
Typed Name of Authorized Individual

_____
Date

NOTE: The penalty for making false statements in offers or bids is prescribed in 18 U.S.C. 1001.

Certification for Contracts, Grants, Loans and Cooperative Agreements

K-1 - 52.252-1 Solicitation Provisions Incorporated by Reference. (FEB 1998)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blanks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of these provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or

SECTION K- Representations, Certifications and Other Statements of Offerors (continued)

offer. Also, the full text of a solicitation provision my be accessed electronically at this/these address(es):

http://www.arnet.gov.far

52.203-11 Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions. (APR 1991)

52.204-5 Women-Owned Business (Other Than Small Business. (MAY 1999)

K-2 - Solicitation Provisions Incorporated in Full Text

52.204-3 Taxpayer Identification. (OCT 1998)

(a) Definitions.

"Common parent," as used in this provision, means that corporate entity that owns or controls an affiliated group of corporations that files its Federal income tax returns on a consolidated basis, and of which the offeror is a member.

"Taxpayer Identification Number (TIN)," as used in this solicitation provision, means the number required by the Internal Revenue service (IRS) to be used by the offeror in reporting income tax and other returns. The TIN may be either a Social Security Number or an Employer Identification Number.

(b) All offerors are required to submit the information required in paragraphs (d) through (f) of this provision to comply with debt collection requirements of 31 U.S.C. 7701(c) and 3325(d), reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M and implementing regulations issued by the IRS. If the resulting contract is subject to the reporting requirements described in Federal Acquisition Regulation (FAR) 4.904, the failure or refusal by the offeror to furnish the information may result in a 31 percent reduction of payments otherwise due under the contract.

(c) The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror's relationship with the Government (31 U.S.C. 7701(c)(3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror's TIN.

SECTION K- Representations, Certifications and Other Statements of Offerors (continued)

(d) Taxpayer Identification Number (TIN).
__ TIN:_____
__ TIN has been applied for.
__ TIN is not required because:
__ Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the U.S. and
does not have an office or place of business or a fiscal paying agent in the U.S.;
__ Offeror is an agency or instrumentality of a foreign government;
__ Offeror is an agency or instrumentality of a Federal Government.

(e) Type of organization
__ Sole proprietorship;
__ Partnership;
__ Corporate entity (not tax-exempt);
__ Corporate entity (tax-exempt)
__ Government entity (Federal, State, or local);
__ Foreign government;
__ International organization per 26 CFR 1.6049-4;
__ Other _____.

(f) Common Parent.
__ Offeror is not owned or controlled by a common parent as defined in paragraph (a) of this provision.
__ Name and TIN of common parent:
Name _____
TIN _____

52.204-6 Data Universal Numbering System (DUNS) Number. (JUN 1999)

(a) The offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation “DUNS” followed by the DUNS number which identifies the offeror’s name and address exactly as stated in the offer. The DUNS number is a nine-digit number assigned by Dun and Bradstreet information Services.

(b) If the offeror does not have a DUNS number, it should contact Dun and Bradstreet directly to obtain one. A DUNS number will be provided immediately by telephone at no charge to the offeror. For information on obtaining a DUNS number, the

SECTION K- Representations, Certifications and Other Statements of Offerors (continued)

offeror should call Dun and Bradstreet at 1-800-333-0505. The offeror should be prepared to provide the following information:

(1) Company name.
(2) Company address.
(3) Company telephone number.
(4) Line of business.
(5) Chief executive officer/key manager.
(6) Date the company was started.
(7) Number of people employed by the company.
(8) Company affiliation.

(c) Offerors located outside the United States may obtain the location and phone number of the local Dun and Bradstreet Information Services office from the Internet Home Page at http://www.customerservice@dnb.com. If an offeror is unable to locate a local service center, it may send an e-mail to Dun and Bradstreet at globalinfo@mail.dnb.com.

52.209-5 Certification Regarding Debarment, Suspension, Proposed Debarment, and Other Responsibility Matters. (MAR 1996)

(a)(1) The Offeror certifies, to the best of its knowledge and belief, that-

(i) The Offeror and/or any of its Principals-

(A) Are _____ are not _____ presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(B) Have _____ have not _____, within a 3-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, state, or local) contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, or receiving stolen property; and

(C) Are _____ are not _____ presently indicted for, or otherwise criminally or civilly charged by a governmental entity with,

SECTION K- Representations, Certifications and Other Statements of Offerors (continued)

commission of any of the offenses enumerated in subdivision (a)(1)(i)(B) of this provision.

(ii) The Offeror has _____ has not _____, within a 3-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.

(2) "Principals," for the purposes of this certification, means officers; directors; owners; partners; and, persons having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a subsidiary, division, or business segment, and similar positions).

This certification concerns a matter within the jurisdiction of an agency of the United States and the making of a false, fictitious, or fraudulent certification may render the maker subject to prosecution under section 1001, title 18, United States Code.

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.

(d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed

SECTION K- Representations, Certifications and Other Statements of Offerors (continued)

when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

52.215-6 Place of Performance. (OCT 1997)

(a) The offeror or respondent, in the performance of any contract resulting from this solicitation, _____ intends, _____ does not intend (check applicable block) to use one or more plants or facilities located at a different address from the address of the offeror or respondent as indicated in this proposal or response to request for information.

(b) If the offeror or respondent checks "intends" in paragraph (a) of this provision, it shall insert in the following spaces the required information:

Place of Performance (Street Address, City, County, State, Zip Code)	Name and address of Owner and Operator of the Plant or Facility if Other than Offeror or Quoter
_____	_____
_____	_____
_____	_____

52.219-1 Small Business Program Representation. (OCT 1998)

(a)(1) The standard industrial classification (SIC) code for this acquisition is 8734 .

(2) The small business size standard is $5.0 million.

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

SECTION K - Representations, Certifications and Other Statements of Offerors (continued)

(b) Representations.

(1) The offeror represents and certifies as part of its offer that it ____ is, ____ is not a small business concern.

(2) (Complete only if offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents, for general statistical purposes, that it ___ is, ___ is not a small disadvantaged business concern as defined in 13 CFR 124.1002.

(3) (Complete only if offeror represented itself as a small business concern in block (b)(1) of this section. The offeror represents as part of its offer that it ____ is, ____ is not a women-owned small business concern.

(c) Definitions. Women-owned small business concern, as used in this provision, means a small business concern--

(1) Which is at least 51 percent owned by one or more women or, in the case of any publicly owned business, at least 51 percent of the stock of which owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

(d) Notice. (1) If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.

(2) Under 15 U.S.C. 645(d), any person who misrepresents a firm’s status as a small or small disadvantaged business concern in order to obtain a contract to be awarded under the preference programs established pursuant to sections 8(a), 8(d), 9, or 15 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall--

(i) Be punished by imposition of fine, imprisonment, or both

(ii) Be subject to administrative remedies, including suspension and debarment; and

SECTION K- Representations, Certifications and Other Statements of Offerors (continued)

(iii) Be ineligible for participation in programs conducted under the authority of the Act.

52.222-22 Previous Contracts and Compliance Reports. (FEB 1999)

The offeror represents that -

(a) It ___ has, ___ has not participated in a previous contract or subcontract subject either to the Equal Opportunity clause of this solicitation;

(b) It ___ has, ___ has not, filed all required compliance reports; and

(c) Representations indicating submission of required compliance reports, signed by proposed subcontractors, will be obtained before subcontract awards.

52.222-25 Affirmative Action Compliance. (APR 1984)

The offeror represents that (a) it ___ has developed and has on file, ___ has not developed and does not have on file, at each establishment, affirmative action programs required by the rules and regulations of the Secretary of Labor (41 CFR 60-1 and 60-2), or (b) it ___ has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

52.223-1 Clean Air and Water Certification. (APR 1984)

The Offeror certifies that -

(a) Any facility to be used in the performance of this proposed contract is ___ , is not ___ listed on the Environmental Protection Agency (EPA) List of Violating Facilities;
(b) The Offeror will immediately notify the Contracting Officer, before award, of the receipt of any communication from the Administrator, or a designee, of the EPA, indicating that any facility that the Offeror proposes to use for the performance of the contract is under consideration to be listed on the EPA List of Violating Facilities; and
(c) The Offeror will include a certification substantially the same as this certification, including this paragraph (c), in every nonexempt subcontract.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

L-1 - General Instructions

Your proposal must be prepared in accordance with the General Instructions, Business Proposal Instructions, and the Statement of Work contained in Part I, Section C of the Request for Proposal (RFP).

The following instructions establish the acceptable minimum requirements for the format and content of proposals. Special attention is directed to the requirements for a business proposal to be submitted in accordance with these instructions.

The penalty for making false statements in offers is prescribed in 18 USC 1001.

A. Submission of Proposals: All documents required for responding to this RFP should be placed in the following order when submitting proposals:

1. COVER PAGE - with RFP title, RFP number, and name of organization. Also, indicate on cover page either:

(a) ORIGINAL PROPOSAL (signed)

(b) COPY OF PROPOSAL

2. BUSINESS PROPOSAL - Your proposal shall include cost and pricing data in sufficient detail to establish the reasonableness of your proposed price/cost. In addition, you must submit one (1) copy of the Representations and Certifications (Section K).

In addition, one (1) copy of the business proposal shall be submitted to the Co-Project Officer in the FDA Regional/District Office.

B. Alternate Proposals. You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements, provided that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interest of the Government. Alternative proposals, or deviations from any requirement of this RFP, shall be clearly identified.

Section L - Instructions, Conditions, and Notices to Offerors (continued)

C. Restriction on Disclosure and Use of Data (APR 1984) (HHSAR 352.215-12). The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act:

LEGEND

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C 552, as amended, (the Act) as determined by Freedom of Information (FOI) Officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc., by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI Officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act. If a contract is awarded to the offeror as a result of, or in connection with the submission of this proposal, the

Government shall have the right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

Section L - Instructions, Conditions, and Notices to Offerors (continued)

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose including the release of the information pursuant to requests under the Act.

The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

In addition, the offeror should mark each page of data it wishes to restrict with the following legend:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

D. Your proposal must stipulate that it is predicated upon all the terms and conditions of this RFP.

E. It is understood that your proposal will become part of the official file.

L-2 - Business Proposal Instructions

Your business proposal shall consist of three parts: Cost and pricing data, other administrative data, and representations and certifications.

The business proposal should be specific and complete in every detail. To reduce subsequent requests to offerors for additional data, the following paragraphs provide guidance on preparing your business proposal.

A. Cost or Pricing Data

You must submit, as a minimum, cost proposals fully supported by cost and pricing data adequate to establish the reasonableness of the proposed amount.

Section L - Instructions, Conditions, and Notices to Offerors (continued)

Submit a detailed breakdown of estimated costs for each task (i.e., Inspections, Samples, and Visits) proposed as well as for any Options. For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated below. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

The proposal shall be submitted in such a way and in such detail as to positively identify all costs and related data in support of the cost proposal. The offeror shall identify all cost or pricing data including historical performance data. Cost or pricing data refers to the portion of the offeror's submission which is factual. The requirement for cost or pricing data is satisfied when all facts reasonably available to the Contractor up to the time of agreement on cost/price, and which might reasonably be expected to affect the price negotiations are accurately disclosed to the Contracting Officer or their representative.

In completing your proposal and supporting documents, you should consider the following:

B. Direct Materials

Your proposal should separately show any major items (those representing $2,000 or 10% of the direct materials cost, whichever is lower) of direct materials and their estimated costs. It should also show the basis for the estimate, e.g., competitive bids, catalog prices or vendor quotations which are the basis for the proposal, and name of proposed vendors.

C. Direct Labor

Submit supporting schedules indicating types or categories of labor, together with person-hours. If you use anything other than actual hours, state the basis of the full-time equivalency, i.e., 2,000 hours, 2080 hours, etc.

Section L - Instructions, Conditions, and Notices to Offerors (continued)

Indicate whether current rates or escalated rates are used. If escalation is included, state the degree (percent) and methodology, e.g., annual flat rate applied to a base rate as of a specific date - or a mid-point rate for the period of performance. Include copies of salary rate schedules for all labor categories proposed.

State whether any additional direct labor (new hires) will be required during the performance period of this acquisition. If so, state the number required and anticipated date of hire.

D. Overhead, General and Administrative Expense

Unless your proposed burden rate(s) has recently been accepted by an agency of the U.S. Government, detailed projected estimates of the various items which are included in the total overhead pools are required. These projected estimates should be based upon past actuals as well as upon the planned mode and level of operation during the period in which effort is to be expended under the subject contract. These estimates should take into consideration all operating changes. Details of cost incurred in the previous fiscal year and current year to date should also be presented. If you have an approved indirect cost rate agreement, it is recommended that you attached a copy of the agreement to your proposal.

E. Special Testing

Include details of special testing (labor, material and overhead), attaching a separate schedule, if necessary. Show the basis of the estimate.

F. Special Equipment

If special purpose equipment is being proposed, provide a description of the item(s), details of the proposed cost including competitive prices, and a justification as to why the Government should furnish the equipment or allow its purchase with contract funds. (See the paragraphs below of this section for policy on equipment.)

If fabrication by the prime contract is contemplated, include details of material, labor and overhead.

Section L - Instructions, Conditions, and Notices to Offerors (continued)

G. Travel Expense

Attach a schedule indicating the estimated number of person-trips required, destinations, mode and cost of transportation, and the number of days of subsistence per trip. Identify and support any other special transportation costs attributable to the performance of this project.

H. Consultant Service

Consultant service should be explained by indicating the specific area in which such service is to be used. Identify the contemplated consultants. State the number of days of such service estimated to be required and the consultant's quoted rate per day, and indicate the number of hours per day in which work will be performed. State whether the consultant has received the proposed rate in performing similar services for other contractors.

I. Other Direct Costs

Special direct taxes, such as Federal excise, state franchise, or personal property taxes directly applicable to this acquisition should be identified, including basis of recovery.

Taxes from which exemptions are available to the contractor directly, or afforded the Government when the procuring agency makes available a certificate of exemption, should not be included in the cost proposal.

When the costs of materials for publication of reports required under the contract are included in your proposal, indicate the approximate total number of pages contemplated in the reports.

The cost of computer time should be supported. Explain what is included in the rate.

While the above are representative of other direct costs, they are not intended to be all-inclusive of the items which may be contained in your cost proposal.

J. Equipment

It is HHS policy that contractors will provide all equipment and

Section L - Instructions, Conditions, and Notices to Offerors (continued)

facilities necessary for performance of contracts. Exception may be granted to furnish government-owned property or to authorize purchase with contract funds, only when approved by the head of the procuring activity. If additional equipment must be acquired, the offeror shall include in your proposal the description, estimated cost of each item, and whether you will furnish such items with your own funds.

K. Government-Owned Property

The offeror shall identify Government-owned property in your possession and/or property acquired from Federal funds, for which you have title and is proposed to be used in the performance of the prospective contract.

L. Control of Government Property

The management and control of any Government property shall be in accordance with DHHS Publication entitled, “Contractor’s Guide for Control of Government Property,” dated 1990, a copy of which will be provided upon request.

M. Other Administrative Data

1. Financial Capacity

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. (If not, indicate the amount required and the anticipated source.)

2. Representations and Certifications

The Representations and Certifications (Section K) are required by public law, acquisition regulations, or acquisition policy.

One (1) copy of the Representations and Certifications, as contained in Section K of this RFP, must be completed by the offeror and returned as a part of the Business Proposal.

L-3 - 52.252-1 Solicitation Provisions Incorporated by Reference.(FEB 1998)

This solicitation incorporates one or more solicitation

Section L - Instructions, Conditions, and Notices to Offerors (continued)

provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blanks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of these provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision my be accessed electronically at this/these address(es):

http://www.arnet.gov.far

52.253-1 Computer Generated Forms. (JAN 1991)

L-4 - Solicitation Provisions Incorporated in Full Text

52.216-1 Type of Contract. (APR 1984)

The Government contemplates award of a fixed-price type contract resulting from this solicitation.

52.233-2 Service of Protest. (AUG 1996)

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Food and Drug Administration
ORA Support and Assistance Management Branch, HFA-521
Attn.: Contracting Officer
5600 Fishers Lane, Room 2129
Rockville, Maryland 20857

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

Section L - Instructions, Conditions, and Notices to Offerors (continued)

L-5 - Cost of Proposal Preparation

The solicitation does not commit the Government to pay any cost for the preparation and submission of a proposal. It is also brought to your attention that the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed acquisition.

SECTION M - EVALUATION FACTORS FOR AWARD

The Section is non applicable to this Request for Proposal.